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OxyContin Special

In this Issue

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*O*xycodone

*I*ntroduction

Oxycodone abuse has been a continuing problem in the United States since the early 1960's. In passing the Comprehensive Controlled Substances Act of 1970 (CSA), Congress placed oxycodone in Schedule II (CII). In spite of its CII status, oxycodone continued to be abused. The abuse of a new sustained-release formulation of oxycodone, known as OxyContin®, has escalated over the last year. Drug abuse treatment centers, law enforcement personnel, and pharmacists initially reported an increase in the abuse of these sustained-release products in Maine, Virginia, West Virginia, Ohio, Kentucky, and

Maryland. The problem has now expanded throughout the United States. The estimated number of emergency department (ED) episodes involving oxycodone were stable from 1990 through 1996. However, the number of ED episodes doubled from 1996 to 1999: 3,190 episodes in 1996 to 6,429 in 1999.

***L*icit *U*ses**

Oxycodone is an effective analgesic for mild to moderate pain control, chronic pain syndromes, and for the treatment of terminal cancer pain. Five milligrams (mg) of oxycodone is equivalent to 30 mg of codeine when administered orally. Oxycodone and morphine are equipotent for pain control in the normal population; 10 mg of orally-administered oxycodone is equivalent to 10 mg of subcutaneously administered morphine. Oxycodone is considered to be in all respects morphine-like and, in spite of the chemical relationship to codeine, closer to morphine than to codeine in its dependence liability. OxyContin® is a sustained, controlled release formulation of oxycodone containing no acetaminophen like Percodan®. Its formulation was designed for use in moderate to severe pain of prolonged duration. The formulation also provides for twice a day drug administration.

***C*hemistry/*P*harmacology**

Oxycodone is a semi-synthetic opioid structurally related to codeine and is approximately equipotent to morphine in producing opiate-like effects. The first report that oxycodone, sold under the brand name *Eukodal*, produced a "striking euphoria" and habituation symptoms was published in Germany in the 1920's. While oxycodone is metabolized by the liver to oxymorphone, the physiological and behavioral effects are not related to, nor dependent on, the formation of this metabolic by-product.

***I*llicit *U*ses**

Oxycodone is abused for its opiate-like effects. In addition to its equipotency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) administration. Many dosage forms are available. Oxycodone's behavioral effects can last up to five hours. The sustained-release formula has a longer duration of action (8-12 hours). The drug is most often administered orally. A recent study[(1)] comparing the only controlled release product containing oxycodone (OxyContin®) and morphine (MS Contin®) reported that OxyContin® was twice as potent as MS Contin®. The growing awareness and concern about AIDS and blood borne pathogens easily transmitted by syringe needle use, has made the oral bioavailability of oxycodone attractive to the typical opiate abuser.

As with most opiates, the adverse effects of oxycodone abuse are dependence and tolerance development. Oxycodone's co-formulation with acetaminophen has also increased the likelihood of acetaminophen-induced hepatic necrosis with chronic dosing. Its availability in sustained-release formulations has increased the dosage forms from 10 mg up to 160 mg per tablet, making the sustained release, single entity formulation more attractive to opiate abusers and doctor-shoppers than traditional oxycodone formulations. While the original idea of polymer-formulations of oxycodone was to reduce the likelihood of misuse with high dosage forms, opiate abusers quickly learned the ease of extraction of the molecule from the polymer formula and have been injecting or snorting the dissolved tablets or crushing and ingesting the tablets in spite of the polymerization and because of its' higher dosage formulations.

***U*ser *P*opulation**
Every age-group has been affected by the relative ease of oxycodone availability and the perceived safety of these products by professionals. Sometimes seen as a "white collar" addiction, oxycodone abuse has increased among all ethnic and economic groups.

***I*llicit *D*istribution**
Oxycodone-containing products are available in tablet, capsule, and liquid forms. A variety of colors, markings, and packaging are available.

The major method of providing oxycodone to the illicit market has been through forged prescriptions, professional diversion through unscrupulous pharmacists, doctors, and dentists, "doctor-shopping", and large-scale thefts. Oxycodone sells for $0.50 to $1.00 per mg. A 40 mg tablet is sold for $25 - $40, and the 80 mg tablets are being sold for $65 - $80. The more recent 160 mg tablets do not have a stable price at this time, but sell for in excess of $100 per tablet.

(1) Curtis GB, Johnson GH, Clark P, Taylor R, Brown J, O'Callaghan R, Shi M, Lacouture; (1999) Relative potency of controlled-release oxycodone and controlled-release morphine in a postoperative pain model. *Eur J Clin Pharmacol* 55:425-429.

***P*oint of *C*ontact**
Comments and additional information are welcomed by the Drug and Chemical Evaluation Section:
telephone: 202-307-7183
Facsimile: 202-307-8570

*P*rescription *D*rugs *B*ecoming a *C*oncern

An article obtained from the *Washington Post*

Four million Americans are abusing prescription drugs, including sleep-deprived people who become addicted to sedatives and family members who sell spare pills on the street, the government says. Pharmaceuticals designed to relieve pain, calm stress or bring on sleep provide great benefit for millions, but when the drugs are used for non-medical reasons, they can lead to addiction and damaged health, said Alan I. Leshner, head of the National Institute on Drug Abuse (NIDA).

Leshner announced at a news conference Tuesday [April 10, 2001] that the NIDA and seven organizations representing the elderly, pharmacies, drug manufacturers, and patients are starting a campaign to combat what he called "a dangerous new drug abuse trend" – the non-medical use of prescriptions.

Calvin Anthony, vice president of the National Community Pharmacists Association and one of a group of experts from the prescription drug industry at the news conference, estimate that misuse and abuse of medication has more than a $100 billion impact on the nation's health care costs. The experts said that many patients taking sedatives, stimulants, tranquilizers, pain killers, or opioids begin to use the pills inappropriately and can slip into an addiction cycle that dominates their lives and damages their health. "Nobody starts out to be addicted," Leshner said. "While prescription drugs can relieve a variety of medical problems and improve the lives of millions of Americans, they can be dangerous, addicting, and even deadly when used non-medically," he said.

The experts said that patients with chronic pain often keep supplies of drugs in their homes for legitimate use and, in some cases, the drugs are stolen by family members for sale on the street. Morphine is often used in large doses by patients with terminal cancer or other conditions and stolen packages of the drug are in high demand on the street.

Some people recovering from surgery use pain-relievers for longer than needed and eventually become addicted. Poor sleepers take sedatives and may mix them with alcohol or other drugs. Eventually, they need more and more of the drug to achieve the same effect. Patients habituated to the drugs may "doctor shop" to find physicians who will prescribe the pills and some addicts will establish accounts at different pharmacies to disguise the number of pills they are actually using.

Ritalin®, or methylphenidate, a drug commonly used to treat the three to five percent of America's children with attention-deficit hyperactivity disorder, is becoming a frequently abused stimulant, NIDA said. The drug is being crushed and snorted, dissolved and injected, or mixed with street drugs to create what is called a "speedball." There have been reports of non-medical use of methylphenidate in Baltimore, Boston, Detroit, Minneapolis, Phoenix, and Texas, NIDA said.

Leshner said that while everybody can potentially abuse prescription drugs, the risk is greatest among women, the elderly, and adolescents. He said a 1999 study showed that of the four million people who used prescriptions for non-medical purposes, half were abusing the medications for the first time that year. This shows prescription abuse is growing, he said.

An increase in prescription drug abuse has accompanied a rapidly rising trend in the legitimate use of mood-altering medications. NIDA said that from 1990 to 1998, new users of pain relievers rose by 181 percent; new use of tranquillizers went up 132 percent; people starting taking sedatives went up by 90 percent, and the use of stimulants rose by 165 percent.

The agency said that about 17 percent of Americans age 60 and older are affected by prescription drug abuse. Leshner said that is because this age group uses about three times more of the drugs than do young people. Women, said Leshner, are two to three times as likely to be diagnosed as needing drugs, such as sedatives, and are about two times as likely to become addicted. Prescription drug abuse among adolescents, age 12 to 17, and among young adults, 18 to 25, is particularly damaging to health because "their brains are still developing" and the effects of overuse of the drugs be "particularly severe," said Leshner.

Leshner said people who abuse prescription drugs are generally of a different population group than those who use street drugs such as heroin, crack or cocaine. He estimated there were about five million "hard-core street addicts."

*U*seful *I*nternet *S*ites

National Institute on Drug Abuse (NIDA)
http://www.nida.nih.gov
or
http://www.drugabuse.gov

Substance Abuse and Mental Health Services Administration (SAMHSA)
http://www.samsha.gov

National Institute of Justice
http://www.ojp.usdoj.gov/nij

Monitoring the Future
http://www.isr.umich.edu/src/mtf

National Household Survey on Drug Abuse
http://www.icpsr.umich.edu/SAMHSA/nhsac.html

Arrestee Drug Abuse Monitor (ADAM)
http://www.adam-nij.net

Drug Abuse Warning Network (DAWN)
http://www.health.org/pubs/dawn/index.html
or
http://www.samhsa.gov/OAS/dawn/dwnfiles.html

Bureau of Justice Statistics
http://www.ojp.usdoj.gov/bjs

Office of National Drug Control Policy
http://www.whitehousedrugpolicy.gov

U.S. Food and Drug Administration
http://www.FDA.gov

National Association of Drug Diversion Investigators (NADDI)
http://www.naddi.org

National Association of Boards of Pharmacy
http://www.nabp.net

and, of course,
DEA's Office of Diversion Control
http://www.DEAdiversion.usdoj.gov

*S*cams

#1 – Posing as a doctor, a man calls in many prescriptions for a controlled substance to different pharmacies in the same general area. Later, he calls back as a police officer to see if the prescriptions are suspicious to the pharmacist. If the pharmacist says yes, the man will not go to that pharmacy. He will usually have a woman accomplice pick up only one or two prescriptions in that area.

Precautions:

- ♦ Verify controlled substance prescriptions often.
- ♦ Any phone calls from police / authorities inquiring about prescriptions – definitely verify those.
- ♦ Always verify the ID of the person picking up a prescription.

#2 – Reports continue to be received from practitioners, consumers, and local and national media regarding unauthorized individuals gaining access to patient information that has been discarded or put out in the pharmacy's trash. Drug seekers are going through the trash and retrieving discarded paper generated in the prescription process, salvaging old bottles, and obtaining other identifying information of legitimate patients. Pharmacies should take steps to ensure that any pharmacy records containing confidential or sensitive information including prescription containers, prescription labels, receipts, notes, telephone messages, and other pharmacy generated documents, be disposed of in such a manner as to maintain patient confidentiality.

Precautions:

- ♦ Shred all paper documents and black out information on discarded containers prior to placing them in the trash.
- ♦ Give empty prescription containers back to patients.

♦ Hold trash in a secure area until the disposal firm can pick it up for incineration or other method of disposal.

U.S. *F*amily *D*octors on *L*ookout for *O*xyContin® *A*busers

By Michele Johnson

Michele Johnson is a government relations representative in the Washington office of the American Academy of Family Physicians

The nation's family doctors have been enlisted in the struggle to stop OxyContin® abuse and make sure only appropriate patients receive this painkiller and other opiods. When used correctly, OxyContin® "has improved pain management and given new hope to thousands suffering from moderate to severe pain," says Bruce Bagley, M.D., Board Chair of the American Academy of Family Physicians (AAFP).

Bagley and other AAFP leaders have launched a campaign to alert the country's family doctors to the practice of "doctor shopping" for painkillers. "Reports of OxyContin® diversion and abuse are disturbing both because of the speed with which this illicit use has occurred in rural, economically depressed communities and because of the deaths reportedly linked with the drug," says Bagley.

What AAFP is & what family physicians are trained to do

The American Academy of Family Physicians represents more than 93,100 family physicians, family practice residents, and medical students nationwide. Family physicians provide comprehensive, coordinated, and continuing care to all members of the family, regardless of age, gender, or health condition. The AAFP is concerned that effective medicines, such as OxyContin®, remain accessible to primary care physicians and their patients who are in chronic pain.

The trend toward OxyContin® abuse has caused the Academy great concern. To address the problem of abuse without harming legitimate medical patients, it is essential to understand the role of the family physician in pain management. "We treat patients of all ages, often seeing patients through the end of their lives. Appropriate pain management is, therefore, an integral aspect of family medicine," says Bagley.

Family physicians complete an extensive three-year residency program in their specialty after graduating from medical school. Family physicians receive training in pediatrics, obstetrics and gynecology, internal medicine, psychiatry and neurology, surgery, and community medicine. As a result, family physicians are the only specialists qualified to treat most ailments and to provide comprehensive health care for people of all ages.

The AAFP recognizes the legitimate law enforcement authority of the federal Drug Enforcement Administration (DEA) and local law enforcement officials to prosecute physicians who are abusing their prescribing authority. Physicians who abuse their prescribing privileges should not be allowed to hide behind their medical license to avoid strong and appropriate law enforcement penalties.

Action to block OxyContin® abuse

State chapters of the Academy are addressing the difficulties of prescribing opioids for long-term pain relief. Continuing medical education seminars on appropriate pain management and screening for abuse are being held in Ohio, Texas, Mississippi, Alabama, and Tennessee. In addition, our chapters in Kentucky, Tennessee, Alabama, and Ohio have published articles outlining the importance of appropriate patient selection, screening for addictions, using non-opioid analgesics as a first resort, and coordinating with pharmacists and other specialists to develop a care plan that prevents diversion and assures long-term monitoring of the patient.

We encourage local DEA Agents to work with the Academy's state chapters. Contact information can be found at:

www.aafp.org/cgi-bin/chapterlookup.p/

At the national level, the AAFP is educating physicians on strategies for identifying all forms of addiction and substance abuse. This spring, the Academy partnered with the National Institute on Drug Abuse (NIDA) and six other organizations to launch the National Initiative on Prescription Drug Misuse and Abuse. In AAFP publications sent to the entire membership, the Academy highlighted the NIDA online publication, *Research Report Series: Prescription Drug Abuse and Addiction*. Relevant AAFP articles can be found in the July issue of *FP Report* at:

www.aafp.org/fpr

Finally, the Academy sponsors continuing medical education conferences that address addicting screening. At the AAFP's 23rd Annual Conference on Patient Education, to be held in Seattle on November 15-18, 2001, the Academy will sponsor a lecture on recognizing the signs and symptoms of prescription medication addiction in specific populations. Also, Ms. Patricia M. Good, Chief of the Liaison and Policy Section of the DEA's Office of Diversion Control, will speak at the Academy's 2001 State Legislative Conference in Bernalillo, New Mexico, November 16-17, 2001.

Summary

In closing, the AAFP is concerned that effective medicines, such as OxyContin®, remain accessible to primary care physicians and their patients who are in chronic pain. Likewise, the Academy is concerned about the illicit use of OxyContin® and has addressed the potential for its abuse in many ways. Through continuing medical education at the state and national level, the Academy has focused on drug abuse and OxyContin® in particular. Please contact the state chapters of the Academy to find out more about the efforts being made across the country to stop the abuse of OxyContin®.

*T*hree *N*ew *P*ublications

The DEA's Office of Diversion Control is pleased to announce the release of three new or newly revised publications.

Diversion and Abuse of Prescription Drugs: A Closer Look at State Prescription Monitoring Programs, produced in concert with the National Alliance for Model State Drug Laws, examines the state efforts to control prescription drugs and controlled substances.

The *Chemical Handler's Manual* has been newly revised to incorporate recent legislation regarding listed chemicals and the

recommendations of the Suspicious Orders Task Force.

The *Pharmacist's Manual: A guide to the Requirements of the Controlled Substances Act* has also undergone a major revision.

All three documents are available for viewing or down loading on the DEA's Internet Web Site:

www.DEAdiversion.usdoj.gov

A limited number of these documents are available in print form and may be obtained by contacting:

DEA, Office of Diversion Control
Liaison & Policy Section
Washington, D.C. 20537

Be sure to indicate which publication you are interested in.

*O*xyContin® - *A S*ense of *B*alance

By John Burke, Commander
Warren County, Ohio Drug Task Force

The recent news media barrage on the abuse of OxyContin® has caused an acute awareness of the drug's potential for abuse. The news of over 200 people arrested in eastern Kentucky and southwestern Virginia slammed into the headlines earlier this year.

Prior to that, Maine and Ohio had indicated significant patterns of abuse of OxyContin®. The fact that this news hit during February, which is "sweeps" month, only fueled the media fire.

Scores of "so called" experts, including myself, were bombarded with interview requests by the local and national press on the OxyContin® issue. Most of my peers that I spoke to, and myself, were frustrated with the media when we were interviewed. They were anxious to hear stories of OxyContin® abuse, but were largely disinterested in comments that the drug had a very legitimate function with the vast majority of its users.

I recently invited a local television station to spotlight a pharmaceutical diversion investigator that I hired to address the overall problem of prescription drug abuse in our county. They photographed him meeting pharmacists in our county and allowed him a brief statement about drug diversion. They had asked about OxyContin®, and I told them I did not know how much of a problem the drug was in our area until I got feedback from my new investigator; until he had some time to gain experience in our area.

The story aired two nights later and I knew there was a problem when I saw the promotional piece. The story strongly insinuated that I hired the investigator because of the OxyContin® abuse issue! This, of course, was totally untrue, but rebuttal opportunities are few and far between.

When abused, OxyContin® is crushed and either snorted or prepared for injection into the body. It allows the abuser to get their rush of oxycodone, exactly what they crave in their daily pursuit of another "fix." This method is nothing new, as Percocet®, Percodan®, and Tylox® have been abused this way for years. We encountered addicts injecting 60-70 of these pills a day to satisfy their habits.

Of course, it's exactly the opposite of what the legitimate pain patient receives when taken orally. The oxycodone is released

gradually during the day, providing the patient with a steady supply of pain relief, and often the ability to be a functional part of our society.

I had a chance to see this first hand recently when I was visiting a large private pharmacy out West. I had the pleasure of meeting a nurse who was an employee of the pharmacy. I observed her counsel pain patients, I had the chance to talk to her, and I watched her work for several hours. It was obvious she had a passion for her job, and did it very well. It was only later that she told me she took two time-released oxycodone a day and wore a fentanyl patch because of chronic pain problems. So much for the stereotype view of the drugged chronic pain patient!

So what's the answer to this dilemma of drug abuse and legitimate pain patients? I think its important to remember that OxyContin® is only the current prescription drug of abuse getting media attention. Hydrocodone has long been the number one prescription drug of abuse, and usually overshadows the oxycodone products in second place. Benzodiazepines, such as alprazolam and diazepam, are another huge source of abuse in the prescription drug world.

In the meantime, the answers to reducing OxyContin® abuse are the same answers for reducing prescription drug abuse in general. Education should be one of the top priorities for the general public, law enforcement, and maybe most importantly, health [care] professionals who prescribe controlled substances.

Practitioners need to become more familiar with how to detect and prevent drug diversion in their practices. Little, if any education is provided in medical school to prepare a physician for the tactics employed by the professional drug seeker. They also need to pay more attention to suspicions of their own staff, and to the pharmacist, who are oftentimes the first to recognize drug diversion.

Health [care] Professionals need to cooperate with law enforcement and regulatory agencies in identifying and prosecuting those involved in these crimes. This includes the small percentage of health[care] professionals who become involved in trafficking in prescription drugs. Physicians trafficking in prescription drugs commonly affect hundreds of their "patients" by perpetuating their addiction or providing thousands of dosage units to be sold on the streets.

[Those in]Law enforcement need to devote considerable more of their resources to the problem of prescription drug abuse. This is a huge problem that can no longer be ignored by my peers and is a significant drug problem in every area of the United States. The 200 arrests made recently in Kentucky and southwest Virginia highlight the positive impact that law enforcement can have on prescription drug abuse.

Finally, although we need to be aggressive when pursing those who would divert or sell pharmaceuticals, we also need to make sure we do not adversely impact legitimate pain patients. We must remember that probably 90 percent or more of all pain medications are taken properly by legitimate patients, and none of us want to see them suffer.

A fringe group has recently called for the removal of OxyContin® from the market because of its recent abuse statistics. Instead, lets not let criminal prescription drug offenders dictate ANY prescription drugs practitioners prescribe and pharmacists dispense. Eliminating any of these proven pharmaceuticals is not only dangerous, but the equivalent of "throwing out the baby with the

bath water." Lets go after the abusers and safeguard those in pain.

*T*he *D*rug *E*nforcement *A*dministration, *C*ontrolled *S*ubstances and *P*ain *M*anagement

by
Larry K. Houck, J.D.
Drug Enforcement Administration
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Liaison and Policy Section, Regulatory Unit

At the time this article was written, Mr. Houck was a staff coordinator with the Drug Enforcement Administration's (DEA) Office of Diversion Control in Washington, D.C. He was a DEA diversion investigator for 10 years in Portland, Oregon, and in the Washington, D.C., area before joining the Regulatory Unit of the Liaison and Policy Section at the DEA headquarters in 1997. He is now employed by the law firm Hymen, McNamara and Phelps in Washington, D.C.

*I*ntroduction

This article is intended to clarify the DEA's position on the use of controlled substances in pain management, while focusing on controlled substance diversion and what healthcare professionals can do to minimize the diversion of controlled pharmaceuticals.

*T*he *D*EA's *P*olicy & *P*ain *M*anagement

In written testimony before the House Judiciary Committee on the Pain Relief Promotion Act of 1999, the American Pharmaceutical Association attributed the under treatment of pain in the United States to six factors. Foremost among these factors was practitioner concern about regulatory oversight. The other factors include: lack of medical training, antiquated fear of addiction, inadequate reimbursement mechanisms, lack of routine assessment, and misunderstanding about side effects. (American Pharmaceutical Association, Statement on Pain Relief Promotion Act of 1996 (H.R. 2260), June 24, 1999.) The implication is that practitioner fear of regulators produces a chilling effect on the use of controlled substances to treat pain effectively.

A common misperception among medical professionals is the belief that the DEA's regulations and policies impede effective pain management. For those of you unfamiliar with the DEA's pain position, the reality is that practitioner fear of the DEA is unwarranted where controlled substances are used appropriately. In fact, far from prohibiting controlled substance use, the Controlled Substances Act, which Congress enacted and which the DEA enforces, its implementing regulations and the DEA all encourage their use where appropriate. The operative word, however, is "appropriate."

*T*he *D*EA's *P*olicy *C*ornerstones

The DEA's position with respect to controlled pharmaceuticals used in pain management rests upon four cornerstones and any discussion about the DEA and pain management must begin there. The Controlled Substances Act and the DEA recognize that many controlled substances "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." *Title 21 of the United States Code (21 U.S.C.), § 801(1)*. Secondly, the regulations state that practitioners are not limited in their ability to administer or dispense narcotic drugs to individuals with intractable pain in

which no relief or cure is possible or none has been found after reasonable efforts. *Title 21, Code of Federal Regulations (21 CFR), § 1306.07(c).*

Thirdly, the regulations require that for a prescription to be valid, it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *21 CFR § 1306.04(a)*. The usual course of professional practice arguably involves such factors as the practitioner's medical specialty, his or her professional training and applicable practice guidelines. Many general practitioners, for example, lack the expertise and professional training necessary to effectively treat severe and chronic pain with Schedule II opioids. Many general practitioners do not understand that not all pain requires opioids and not all pain patients are appropriate candidates to receive opioids. I would note that this test also applies to administration and other dispensings. I would also note that while the prescriber bears responsibility for proper prescribing and dispensing, corresponding responsibility rests with the pharmacist who fills the prescription. *21 CFR § 1306.04(a).*

And lastly, cornerstone number four is the unfortunate reality that opiate analgesics, the controlled substances most commonly prescribed for the treatment of pain, have a high potential for abuse and are frequently diverted to illicit use.

*T*he *D*EA's *D*ual *R*ole

The DEA's mission with respect to illicit controlled substances like heroin and crack, is to eliminate them outright. However, the DEA's role is much more complex when it comes to licit controlled pharmaceuticals. On one hand, the DEA prevents, detects, and eliminates the diversion of controlled pharmaceuticals from legitimate channels to illegal use, while at the same time ensuring their availability for legitimate medical and scientific purposes. To facilitate these goals, Congress through the Controlled Substances Act, established a closed system of controlled substance distribution encompassing manufacturers, distributors, pharmacies, and physicians. Components of this closed system include scheduling of all controlled substances, registration of all controlled substance handlers, record keeping for accountability, security and manufacturing quotas, all under the DEA's oversight.

Despite the closed system, controlled substance diversion occurs in many ways. A physician or pharmacist, for example, may trade drugs for money or sex. A physician or pharmacist may divert drugs for their own personal, non-therapeutic use. "Doctor-shopping" patients may feign illness to acquire drugs, and drugs may be obtained through forged prescriptions. Diverted pharmaceuticals are used for other than legitimate medical purposes including being sold on the street for many times their retail value.

*T*he *D*EA's *I*nquiries

There has been a misperception that the DEA investigates all doctors who prescribe significant quantities of narcotic drugs. Contrary to popular belief, dosage quantities and duration of treatment do not alone trigger DEA investigations because there are numerous legitimate reasons for such prescribing or administration patterns. Quantities and types of drugs involved are frequently components of an investigation but alone cannot trigger anything more than a closer look at the activity in question. Dosage quantities and the number of practitioners issuing prescriptions to a specific patient may result in inquiries about that patient if they appear to be "doctor shopping" or they exhibit drug-seeking behavior.

Many drug abusers and dealers visit numerous practitioners to maximize the number of drugs they can obtain. They then spread their prescriptions over a wide geographic area to avoid detection. When inquiring about these individuals, it is often necessary for the DEA and other law enforcement authorities to contact the practitioners who issued the prescriptions, or those whose signatures were forged. These fact-finding inquiries should not imply that the DEA is investigating the practitioner or that he or she is culpable in any way.

_D_EA _I_nvestigations

The DEA investigates practitioners and pharmacists when there is suspicion of criminal activity specifically the "diversion" or sale of controlled drugs or prescriptions without legitimate need. To proceed with criminal or administrative actions, the DEA must have conclusive evidence of wrongdoing such as providing multiple prescriptions to individual patients in fictitious names to avoid detection; trading drugs for sexual favors or money; or providing controlled substance prescriptions to known abusers despite awareness of actual harm or of their arrests for selling the drugs that he had earlier provided.

The DEA works closely with its state counterparts in many investigations. State medical and pharmacy board investigators sometimes provide the DEA with leads on possible criminal activity; the DEA, in turn, often refers possible "unprofessional practice" or misconduct issues to the Boards. Sometimes we conduct investigations together.

The DEA does not define or regulate standards of medical practice. Once it has been decided that criminal prosecution through a state or federal prosecutor's office or administrative action will be pursued, it becomes necessary to engage medical experts in the review process to determine whether specific conduct clearly falls outside the scope of legitimate medical practice.

_F_ederation of _S_tate _M_edical _B_oards'

"Model Guidelines for the Use of Controlled Substances in the Treatment of Pain"

A much asked question is: "How does a physician know whether his prescribing or administering opiates for pain is appropriate?" The DEA testified in support of the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances in the Treatment of Pain" in March 1998. The DEA endorsed the guidelines because they are consistent with the four cornerstones of the DEA's pain management position referred to earlier. The guidelines are important because they set forth the general principles that doctors should consider in determining legitimate medical need and legitimate medical practice based on clinical grounds. The guidelines are incompatible with the type of practice that leads to willful, criminal diversion of controlled substances by a practitioner unless the practitioner intentionally falsifies medical diagnoses and records.

When applied conscientiously, the guidelines also minimize the risk of diversion through negligence that often occurs when "doctor shoppers" posing as patients feign illness to obtain drugs for street sale or for personal use. For example, the guidelines require a physician when evaluating a pain patient to take a complete medical history and conduct a physical examination. They require the physician to set down a written treatment plan with objectives, and to conduct reasonable follow-ups to continue or modify therapy. The guidelines also require the

physician to comply with applicable controlled substance laws and regulations and to document everything accurately and completely.

When a physician determines that a patient is at risk for medication abuse or has a history of substance abuse, the guidelines suggest a written agreement between the physician and patient outlining patient responsibilities. The guidelines embody a reasonable approach to help maintain the delicate balance between preventing controlled substance diversion and ensuring access by legitimate patients. The guidelines also promote a healthy bona fide physician-patient relationship for the benefit of everyone, especially the patient. I understand that you have copies of these guidelines and that you provide them to practitioners who feel uncomfortable about prescribing opiates for their consideration.

*Q*uantity *L*imits

Provided there is legitimate medical need, a practitioner may issue a prescription to any patient for any quantity of any controlled substance that he or she deems medically appropriate. There are no limits on the quantity of controlled substance dosage units under federal law or regulation that a practitioner may prescribe. Prescriptions for all drugs except for those in Schedule II may be refilled up to five times during a six-month period but there are no restrictions on the quantities that may be dispensed. *21 CFR 1306.22(a).* Prescriptions for Schedule II drugs may not be refilled and a new prescription signed by the prescriber must be provided to the pharmacy for each new supply dispensed. *21 CFR 1306.13(a).* However, some states, and even some insurance providers, do limit controlled substance quantities that practitioners may prescribe.

*T*he *D*EA's *I*nitiatives

While attempting to stem controlled substance diversion, the DEA has simultaneously undertaken a number of initiatives over the past decade designed to facilitate patient access to needed pain medication. Through extensive participation in seminars, meetings, and conferences, the DEA is trying to dispel the misperception that its regulations and policies impede effective pain management. The DEA includes medical specialists in the fields of pain management and addiction treatment as speakers at conferences attended by law enforcement and regulatory officers. As previously mentioned, the DEA provided testimony in support of the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain." The DEA amended the regulations to allow faxing schedule II narcotic prescriptions for home infusion patients, and those in hospices and Long Term Care Facilities (LTCF). *21 CFR 1306.11(f).* The DEA also amended the regulations to allow for the partial filling of Schedule II prescriptions for terminally ill or LTCF patients to accommodate changes in medication needs. *21 CFR 1306.13(b).* In addition, The DEA is currently engaged in a pilot project that may serve as a basis for new regulations that will allow for secure transmission through faxing or e-mailing of prescriptions for substances in all schedules, again to facilitate patient access.

Perhaps the most important of the DEA's activities has involved aggregate production quotas for analgesics. The DEA has worked with industry and healthcare professionals to increase aggregate production quotas and quotas for strong analgesics have increased significantly over 1990 totals. For example, the 1999 aggregate production quota for fentanyl was 10.4 times what it was in 1990.

Nineteen ninety-nine's aggregate production quota for oxycodone was 6.4 times what it was in 1990. The aggregate production quotas for hydrocodone (4.5 times), hydromorphone (3.8 times), and morphine (2.6 times) also increased significantly over the past decade. Additionally, the sheer number of products containing Schedule II substances have increased from three hundred in 1990 to over four hundred in 1997, and over 75 percent of these products are analgesics used to treat pain.

*R*egistrant *R*esponsibilities

Generally, all DEA registrants must provide effective controls and procedures to guard against theft and diversion of controlled substances. *21 CFR § 1301.71(a).* Secondly, a registrant must make a good faith inquiry with the DEA or the appropriate state agency that a recipient of controlled substances, like a doctor or pharmacy is authorized to possess the controlled substance. *21 CFR 1301.74(a).* Lastly, a registrant must design and operate a system to disclose suspicious controlled substance orders, and to report these suspicious orders to the DEA. *21 CFR § 1301.74(b).* Suspicious orders include orders of unusual size, orders that deviate substantially from a normal pattern, and orders of unusual frequency.

*F*orged *P*rescriptions

One of the most common ways to divert controlled pharmaceuticals is through prescription forgeries. Currently, the most commonly forged prescriptions are for: hydrocodone products like Vicodin®, Lortabs®, Lorcet®, and Anexsia®; oxycodone products like OxyContin®, Percodan®, Percocet®, and Tylox®; Methylphenidate, or Ritalin®; and benzodiazepines such as alprazolam, diazepam (or Valium®), and lorazepam.

Characteristics of forged prescriptions may include the following factors: the prescription looks "too good or neat;" quantities, directions, or dosages differ from usual medical usage; the prescription appears to be photocopied; directions on the prescription are written in full with no abbreviations; and lastly, the prescription is written in different color inks or written in different handwriting.

The responsibility for proper prescribing and dispensing of controlled substances rests upon the prescribing physician, but a corresponding responsibility rests with the pharmacist who fills the prescription. *21 CFR § 1306.04(a).* In order to help prevent prescription forgeries, the pharmacist should know the prescriber and his signature. The pharmacist should know or should verify the prescriber's DEA registration number. The pharmacist should know the patient, and the pharmacist should check the date on the prescription order. Perhaps the most effective thing a pharmacist can do, is to verify the prescription and its particulars with the prescribing physician. This can be accomplished with a simple telephone call.

If a pharmacist believes that he has been given a forged, altered, or counterfeit prescription, he should not dispense the medication and he should call the local police. If a pharmacist believes that he has uncovered a pattern of prescription abuses, he should contact his state board of pharmacy and the local DEA office.

*C*onclusion

In conclusion, the one thing I would have you remember with respect to the DEA, controlled substances, and pain management is this: a practitioner may prescribe, administer, or dispense any quantity of any controlled substance so long as there is a

legitimate medical purpose and he or she is acting in the usual course of professional practice. Practitioner concern about the DEA's oversight is unwarranted if the practitioner is handling the controlled pharmaceuticals appropriately based upon legitimate medical need.

If you encounter practitioners concerned about regulatory scrutiny, provide them with a copy of the Federation of State Medical Boards' Guidelines, refer them to the DEA Diversion website:

(www.DEAdiversion.usdoj.gov),

or refer them to the local DEA office. If you encounter potential diversion of controlled substances, report it to your supervisor, and/or contact the DEA. I encourage you to use the DEA as a resource. We have a number of publications on these and other related topics which are available through the DEA Diversion website or by contacting the Liaison and Policy Section at the DEA headquarters. Staffers at the DEA headquarters and diversion investigators in the field are there to advise and assist you.

*R*equest for *H*elp!

In an effort to move into the electronic age, the DEA is exploring the possibility of distributing this and other newsletters via e-mail and/or facsimile. If you currently have an e-mail account and would like to receive the *DEA-Industry Communicator* in this format, please forward your address via facsimile to 202-307-8570. Or, if you wish to receive your copy via facsimile, please send your fax number to the number listed. In either case, be sure to include the newsletter and method of receipt that you wish to use. Thanks for your assistance. Editor

Q and *A*

*A*nswers to *F*requently *A*sked *Q*uestions *R*egarding *O*xyContin®

***Q) W*hat authority does the DEA have to regulate the handling of controlled substances, like OxyContin®?**

A) The DEA's authority to regulate pharmaceutical controlled substances is derived from the Controlled Substances Act (CSA) [21 U.S.C. §§ 801-971]. The CSA mandates that the DEA prevent, detect, and investigate the diversion of legally manufactured controlled substances while, at the same time, ensuring that there are adequate supplies to meet the legitimate medical needs in the United States.

To enable the DEA to achieve these goals, the CSA established five schedules into which controlled substances are separated according to their approved medical use and abuse potential. Schedule I controlled substances are those deemed not to have legitimate medical uses and have a very high potential for abuse. Schedule II substances, including OxyContin®, are approved for medical use and also have a very high abuse potential. Schedules III, IV, and V include controlled substances that have all been approved for

medical use and have diminishing potential for abuse.

The CSA also established a closed system of distribution that includes the registration of controlled substances handlers, including manufacturers, distributors, importers, exporters, practitioners, and pharmacists. Production quotas as well as record keeping and security requirements are designed to enable the DEA to track and safeguard potentially dangerous controlled substances as they are transferred from the manufacturer to the ultimate user.

***Q) I*s the DEA planning to restrict the prescribing of OxyContin® to pain treatment centers or physicians specifically accredited as pain management specialist?**

A) Throughout the DEA's examination of the abuse of OxyContin®, numerous options have been explored and discussed with the healthcare community and pharmaceutical industry. None of these options will be employed unilaterally by the DEA without considering the effects they may have on public health.

The CSA requires that controlled substances be prescribed, dispensed, or administered only for legitimate medical purposes by practitioners acting in the usual course of their professional practice. The CSA and its implementing regulations do not define "legitimate medical purpose" nor do they set standards as to what constitutes "the usual course of professional practice." The DEA relies on the medical community to make these determinations. The DEA has a well-established relationship with experts in the field of pain management and has enlisted their expertise in devising strategies to ensure that OxyContin® and other powerful opioids are appropriately prescribed.

The DEA agrees with pain treatment specialists' assertions that many general practitioners have not received adequate training to address complex chronic pain syndromes. These specialists emphasize that Schedule II opioids are best used as the treatment of last resort for chronic pain; and that when they are used, they should be part of a multi-disciplinary approach to pain management, including physical and psychological therapy. The DEA has strongly supported the establishment of "Model Guidelines for the Use of Controlled Substances in Pain Management" by the Federation of State Medical Boards. These guidelines reflect currently accepted standards that may be used by both medical professionals and regulators in determining the appropriateness of opioid prescribing.

***Q) W*hat is the relationship between the DEA and the Food and Drug Administration (FDA) in regulating drugs like OxyContin®?**

A) The FDA is responsible for approving drugs for medical use. These drugs include those sold over-the-counter, those requiring a prescription, and prescription drugs that are controlled under the CSA. The FDA also sets regulations for the marketing of drugs, including controlled substances.

The DEA does not directly regulate the marketing of controlled substances. However, in keeping with the DEA's mandate to ensure appropriate safeguards against diversion, the DEA is concerned when marketing and advertising tactics appear to create an increased possibility for diversion or misuse. If marketing tactics seem to lead to oversupply or minimize the abuse potential of a controlled substance, the DEA makes every effort to work with pharmaceutical companies and the FDA to find appropriate solutions to these problems.

Q) What evidence does the DEA have to support accounts that OxyContin® is being abused to the extent that has been reported by the media?

A) Since its introduction in 1996, the number of OxyContin® prescriptions dispensed has increased twenty-fold to about six million in 2000. During this same time, medical examiners, drug treatment centers, law enforcement personnel, and pharmacists have reported a substantial increase in the abuse of this product.

Information received from the Drug Abuse Warning Network (DAWN) indicates that instances of emergency department episodes and medical examiners reports involving oxycodone, the active ingredient in OxyContin®, have increased significantly since 1996.

Reports from 20 metropolitan areas within the continental U.S. indicate that oxycodone-related deaths and emergency department episodes have increased 400 percent and 100 percent, respectively.

Most deaths reported in the media and attributed to OxyContin® have generally occurred in areas outside the DAWN system, such as Maine, West Virginia, and rural Kentucky. The DEA has been actively collecting and evaluating data from medical examiners in these areas to more clearly ascertain the extent of abuse problems.

Drug treatment programs have also provided evidence regarding an increase in OxyContin® abuse. Programs in West Virginia, Pennsylvania, Kentucky, and Virginia, the states that have been most severely affected by this trend, report that 50 to 90 percent of newly admitted patients identified OxyContin® as their primary drug of abuse.

Q) What steps are currently being taken to address the widespread abuse of OxyContin®?

A) The DEA's approach to dealing with the abuse and diversion of OxyContin® is consistent with the methods normally used in combating the diversion of pharmaceutical controlled substances. These approaches include liaison with the healthcare community, the pharmaceutical industry, and other domestic and international agencies; education of medical professionals regarding various scams that are used to obtain controlled substances for illicit purposes; and the investigation of suspected diverters.

For a more detailed description of the DEA's strategies, you may access the Office of Diversion Control's web site at www.DEAdiversion.usdoj.gov for the document "Working to Prevent the Diversion and Abuse of OxyContin®" under the listing "What's New."

Q) What strengths of OxyContin® are most commonly abused or diverted?

A) Law enforcement and forensic laboratory data indicate that their exhibits are primarily for the 40 mg. tablets, although all strengths (10 mg., 20 mg., 40 mg., 80 mg., and 160 mg.) have been encountered.

Q) Did the DEA have any part in Purdue's decision to "temporarily suspend" distribution of the 160 mg. strength tablet?

A) The DEA has expressed its concerns to Purdue regarding the diversion and abuse of their OxyContin® products. The DEA recognizes the therapeutic value of long-acting opioids in the treatment of chronic

pain. However, it has been found that the controlled release formulation used in OxyContin® products can be easily compromised. The ability to quickly release a high dose of oxycodone that is intended for slow release, whether intentional or not, makes this product both attractive to abusers and dangerous to individuals who have not developed a tolerance to opioids.

The DEA has not asked Purdue to withdraw the 160 mg. tablet and recognizes that this dosage may be appropriate for a limited number of patients. The Associate Press reported on May 11, 2001, that Purdue stated government pressure played no part in its decision to suspend distribution of OxyContin® 160 mg. tablets. It would not be appropriate for the DEA to speculate about the decision.

***Q) I*s the DEA going to reduce manufacturing quotas for oxycodone, the active ingredient in OxyContin®?**

A) All quotas are reviewed annually to ensure that the amount of controlled substances produced are sufficient to meet the legitimate medical, scientific, research, and industrial needs of the U.S. This review includes a yearly forecast of expected changes in medical use, data from prescription and hospital use, as well as abuse, trafficking, and diversion data. Quotas may be increased or decreased depending on expected needs or excessive supplies. Excessive inventories of any controlled substance heighten the chances of possible diversion.

In the case of oxycodone, the active ingredient in OxyContin®, all relevant data is being reviewed.

The *DEA-Industry Communicator* is a publication of the Drug Enforcement Administration (DEA)'s Office of Diversion Control. It is intended to facilitate communication between the DEA and the industries that it regulates. The editor and staff of the *Communicator* welcome articles and suggestions for topics from readers. Articles submitted for inclusion in the *Communicator* are subject to editing for content and length. All submissions should bear the author(s) name(s) and affiliation and include a statement authorizing publication of the materials.

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